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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/586,718	04/28/2008	Daniel Felix Awengen	3812	8211

278 7590 11/17/2009  
MICHAEL J. STRIKER  
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HUNTINGTON, NY 11743

EXAMINER
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GOSART, TIMOTHY J

ART UNIT	PAPER NUMBER
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3738

NOTIFICATION DATE	DELIVERY MODE
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11/17/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

striker@strikerlaw.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/586,718	<b>Applicant(s)</b> AWENGEN ET AL.	
	<b>Examiner</b> TIMOTHY J. GOSART	<b>Art Unit</b> 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 28 March 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 21-38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 January 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>07/20/2006</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Drawings***

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: **12"**. Page 11, Lines 24-28 appears to contain a typographical error by which rod **12'** in Figure 4a and rod **12"** in Figure 4b are both referred to as rod **12'**. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Claim Objections***

2. Claims 21, 25, and 33 are objected to because of the following informalities: the term "staples" appears to contain a typographical error and is interpreted as "stapes". Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 33 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 33 recites that frequency adjustment includes “a device for changing a point of attachment of said prosthesis.” While similar language is found in the specification, there appears to be no further description of such a device or other means for changing a point of attachment of the invention.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 21-24, 26-29, 31, 33, 34, 37, and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Kurz (US 20020045939). Kurz discloses an elastic ossicular prosthesis comprising clip **41** configured to receive a stapes, and coupled to articulating

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ball-joint connection **42**, which is coupled to a shaft lever for adjustment of frequency transmission, which comprises U-shaped clips **43** for gripping and holding an anvil (Figure 4). The socket of the ball-joint is U-shaped and has sidewalls for receiving the ball (Figure 4). The shaft lever is configured to change in angle to permit frequency adjustment, and may also be attached at different locations within the middle ear. The device is capable of connecting to an active vibration component of a hearing aid; it is noted that there appears to be no specific structural elements of the instant prosthesis which would suggest that the Kurz prosthesis is incapable of such connection.

Alternatively, the prosthesis comprises piston **22** capable of directly connecting by way of opening a cochlea (Figure 2). The prosthesis is formed of a biocompatible synthetic material such as titanium or titanium alloy (Paragraph 9).

### ***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

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not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kurz (US 20020045939) in view of Kurz et al (US 6387128) "Kurz '128". Kurz does not disclose a surface roughness at a point of contact with an ossicle. However, Kurz '128 teaches an ossicular prosthesis comprising a surface roughness at the interface with an ossicular element (Column 2, Lines 6-9). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to provide a surface roughness at an ossicular interface of the Kurz prosthesis, as taught by Kurz '128, for the purpose of providing optimal abutment of the prosthesis against the ossicular element.

10. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kurz (US 20020045939) in view of Prescott (US 5554188). Kurz does not disclose forming the prosthesis of silicone. However, Prescott teaches an ossicular prosthesis formed of silicone (Column 3, Lines 17-22). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to form the Kurz prosthesis of silicone, as taught by Prescott, for the purpose of providing a material known to provide biocompatibility and elasticity for medical implants.

11. Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kurz (US 20020045939) in view of Knox et al (US 20010037151). Kurz does not disclose forming the prosthesis of a shape memory material. However, Knox teaches an ossicular prosthesis formed of nitinol (Paragraph 38). Therefore, it would have been

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obvious to one having ordinary skill in the art at the time of invention to form the Kurz prosthesis of nitinol, as taught by Knox, for the purpose of providing a titanium alloy having the benefits of shape memory readily appreciated of nitinol within the art.

12. Claims 35 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kurz (US 20020045939) in view of Hurst (US 3710399). Kurz does not disclose an additional mass clipped to the prosthesis. However, Hurst teaches an ossicular prosthesis comprising magnet **3** having a mass and clipped to shafts **1** and **2** of the prosthesis (Figure 2). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to include an additional mass clipped to the Kurz prosthesis, as taught by Hurst, for the purpose of permitting frequency response according to a predetermined protocol.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIMOTHY J. GOSART whose telephone number is (571)270-7826. The examiner can normally be reached on Monday-Thursday 8:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, CORRINE McDERMOTT can be reached on (571)272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/T. J. G./  
Examiner, Art Unit 3738

/Brian E Pellegrino/  
Primary Examiner, Art Unit 3738